

**GOVERNMENT OF INDIA  
MINISTRY OF HEALTH AND FAMILY WELFARE  
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA  
UNSTARRED QUESTION NO.4528  
TO BE ANSWERED ON 19<sup>TH</sup> JULY, 2019**

**R&D OF GENERIC MEDICINES**

**4528. SHRI SUNIL BABURAO MENDHE:  
SHRI RAVINDRA KUSHAWAHA:  
MS. DIYA KUMARI:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) the total amount spent for the research and development of generic medicines during the last three years, particularly their manufacturing in Rajasthan, Maharashtra, Gujarat and Uttar Pradesh;
- (b) the details of the steps taken by the Government to ensure the quality of generic medicines;
- (c) whether the branded medicines have been proven of low quality, ineffective and spurious during quality tests;
- (d) if so, the number of such medicines that have been identified; and
- (e) the specific steps taken by the Government to check it?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SHRI ASHWINI KUMAR CHOUBEY)**

(a): There is no definition of 'generic drugs' prescribed in the Drugs & Cosmetics Act & Rules made thereunder. However, generic medicines are generally those which contain same amount of same active ingredient(s) in same dosage form, and are intended to be administered by the same route of administration as that of branded medicine. No data is available regarding amount spent for research and development of generic medicines.

(b): The Government is committed to ensuring that the quality, safety and efficacy of drugs are not compromised. With this in view, the Government has taken a series of measures including strengthening of legal provisions, workshops and training programmes for manufacturers and regulatory officials and measures such as risk based inspections.

(c) to (e): The quality of the drugs imported, manufactured and sold in the country is regulated under the provisions of Drugs and Cosmetics Act, 1940 and Rules made there under. The medicines, whether branded, generic or branded - generic, imported or manufactured for sale, distribution in the country, are required to comply with the same standards as specified in the Second Schedule to the Drugs and Cosmetics Act, 1940. State Licensing Authorities are empowered to take action in case of any non-compliance.